WHAT IS CLAIMED IS:

1. A press punch for fabricating compacts comprising:

an upper guide section defining an aperture for receiving a first tablet punch;

a threaded adjuster operatively coupled to a second tablet punch;

a die; and

a lower guide section defining a passage, said passage having a first profile, for receiving said die, and a second profile, for threadably engaging said threaded adjuster;

wherein the upper guide section and the lower guide section are adapted and configured to cooperate with each other in a manner to sealingly enclose said die.

2. A press punch as recited in Claim 1, wherein said second tablet punch is movable with respect to said threaded adjuster.

3. A press punch as recited in Claim 2, wherein the threaded adjuster defines an adjuster recess.

4. A press punch as recited in Claim 3, further comprising a tablet ejection plug.

5. A press punch as recited in Claim 4, wherein the tablet ejection plug is adapted and configured to couple within said adjuster recess.

6. A press punch as recited in Claim 5, wherein upon coupling of the ejection plug into the adjuster recess said second tablet punch moves with respect to said threaded adjuster.

7. An enclosed press punch assembly for creating small compacts from small quantities of material, comprising:

an integral guide section having an upper end and a lower end surface, said integral guide section defining a recess; and

a die having a top surface and a bottom surface adapted and configured to sealingly fit within a medial portion of said recess of said integral guide section;

a movable upper punch adapted and configured to sealingly fit within said recess of said integral guide section from said upper end surface to said top surface of said die; and

a movable lower punch adapted and configured to sealingly fit within said recess from said lower end surface to said bottom surface of said die.

8. A press punch for fabricating compacts comprising:

an upper guide section defining an aperture for receiving a first tablet punch;

a selectively positionable adjuster operatively coupled to a second tablet punch;

a die; and

a lower guide section defining a passage, said passage having a first profile, for receiving said die, and a second profile, for engaging said selectively positionable adjuster;

wherein the upper guide section and the lower guide section are adapted and configured to cooperate with each other in a manner to sealingly enclose said die.

9. A press punch as recited in Claim 8, wherein said second tablet punch is movable with respect to said selectively positioned adjuster.

10. A press punch as recited in Claim 9, wherein the selectively positioned adjuster defines an adjuster recess.

11. A press punch as recited in Claim 10, further comprising a tablet ejection plug.

12. A press punch as recited in Claim 11, wherein the tablet ejection plug is adapted and configured to couple within said adjuster recess.

13. A press punch as recited in Claim 12, wherein upon coupling of the ejection plug into the adjuster recess, said second tablet punch moves with respect to said selectively positionable adjuster.

14. A method of evaluating new drug candidate formulations for fabrication by compaction, the method comprising the steps of:

(a) determining the flow properties of the new drug candidate formulations;

(b) preparing compacts of said new drug candidate formulations;

(c) preparing granules from the compacts of step (b) made from said new drug candidate formulations which do not demonstrate all three of the following flow properties: (1) a Carr Index below about 15%; (2) a static angle of repose between about 20° and about 40°, (3) gravity free flow;

(d) characterizing the flow properties of granules produced in step (c);

(e) recompressing the granules of step (c) which demonstrate all three of the following flow properties: (1) a Carr Index below about 15%; (2) a static angle of repose between about 20° and about 40°, (3) gravity free flow;

(f) evaluating the recompressions of step (e) for acceptable hardness and release of the new drug candidate.

15. A method as recited in Claim 14, wherein the compacts are formed from less than about fifty grams of the new drug candidate formulation.

16. A method for determining if a formulation, is suitable for dry granulation by roller compaction, said method comprising:

(a) preparing a plurality of material compacts on a linear press utilizing a plurality of compression forces starting from the minimal force necessary to produce a visibly non-friable compact;

(b) milling the plurality of material compacts through a mesh of sufficient size to form granule fractions rather than fine powder fractions;

(c) measuring one or more properties of the granule fractions of step (b) selected from the group of properties consisting of: (1) the Carr index, (2) the static angle of repose, (3) particle size distribution, (4) particle morphology;

(d) determining those granule fractions having at least one of the following characteristics: (1) a Carr Index below about 15%; (2) a static angle of repose between about 20° and about 40°, (3) a particle size distribution such that less than about 25% of the total mass of the granule fraction passes through a 50 micron sieve, (4) generally smooth particle morphology; and

(e) adjudging the material or material formulation suitable for dry granulation by roller compaction based on one or more of the granule fractions of step (d) being recompressible into a non-friable compaction.

17. A method for setting the compaction pressure of a production scale roller compactor for a particular material/material formulation comprising:

(a) preparing a plurality of compacts of the material on a linear press utilizing a plurality of compression forces;

(b) milling the plurality of material compacts through a mesh of sufficient size to form granule fractions rather than fine powder fractions;

(c) determining the granule fraction having the best flow as characterized by the fraction's Carr Index and Angle of Repose;

(d) setting the compaction pressure of a production scale roller compactor to a pressure approximately (± 20%) the pressure used to form the compact from which the granule fraction having the best flow was milled.

18. A method as recited in Claim 17, wherein the compacts of step (a) comprise less than fifty grams of material.